REMARKS

I. Preliminary Comments

The independent claims have all been amended to recite that the amount of resistant starch is at least 20% of the total starch and 15% of the total carbohydrate content which amendments are supported at page 9, lines 9 and 14 of the disclosure. The inventors have shown that consumption of a diet high in resistant starch and unsaturated fats or lipids results in desirable effects on carbohydrate and fat metabolism. In particular, the inventors have shown beneficial results resulting from diets which replace at least 15% of an individual's daily carbohydrate intake with amylase resistant starch and at least 10% of the individual's saturated fat intake with unsaturated fat.

Applicants note, with gratitude that the previous rejections under Laughlin in view of Watanabe, U.S. Patent 5,300,311 and Garg, American Journal of Clinical Nutrition, 1998 have now been withdrawn.

II. Outstanding Rejections

Claims 13-25, 36 and 37 stand rejected under 35 U.S.C. § 112 (second paragraph) as being indefinite.

Claims 13, 14, 16-19, 21-23, 36 and 37 stand rejected under 35 U.S.C. §102(b) as being anticipated by Brown et al., WO 96/08261.

Claims 13-20, 22-25, 36 and 37 stand rejected under 35 U.S.C. § 103(a) as being obvious over Brown et al.

Claims 13-14, 16-24, 36 and 37 stand rejected under 35 U.S.C. §103(a) as being obvious over the disclosure of Green et al., U.S. Patent 5,792,754.

III. Patentability Arguments

A. The Rejection Under 35 U.S.C. §112 (second paragraph) Should be Withdrawn

The rejection on the basis that the claims are indefinite should be withdrawn because those of ordinary skill would understand how to consistently determine grams and percentages of resistant starch content as recited by the claims. Those of ordinary skill in the art would have measured resistant starch levels by practice of the method of the McCleary method described in of McCleary, Proc. 42nd RACI Cereal Chem. Conf. Christchurch, NZ Ed. VJ Humphrey-Taylor pp 304-312 (1992). The McCleary method was known since 1992 and was approved by the Association of Official Analytical Chemists [AOAC] as the only approved method for determining the amount of resistant starch.

Those of ordinary skill would have recognized from Applicants' specification that the McCleary method be used to determine resistant starch levels. First, Applicants' specification teaches at para. 0035:

> "[0035] As used in this specification, the term "resistant starch" includes those forms defined as RS1, RS2. RS3 and RS4 as defined in Brown. McNaught and Moloney (1995) Food Australia 47:272-275."

Brown, et al., Food Australia, (1995) in turn taught that "resistant starch" was defined as "the sum of starch and products of starch degradation not absorbed in the small intestine of healthy individuals" (pg. 272, col. 2 lines 8-14). Brown then cited Prosky et al., J. Assoc, Off. Anal. Chem. 71(5):1017 (1988) as providing "the officially accepted method of the Association of Analytical Chemists" for detecting resistant starch.

Applicants' specification also refers to Goodman Fielder WO 94/14342 and WO 94/03049 which in turn instruct use of the McCleary method. WO 94/03048 describes the analysis by the method of McCleary, Proc. 42nd RACI Cereal Chem. Conf. Christchurch, NZ

Ed. VJ Humphrey-Taylor pp 304-312 (1992). While WO 94/14342, (which corresponds to Brown U.S. 6,303,174) refers to the analytical methods of both Muir et al. and McCleary et al., it is noted that the McCleary and Muir methods give results which are within the accepted experimental error and thus are considered to be the same.

In addition, the prior art as reflected in numerous Brown et al., Goodman Fielder Limited issued US patents took a consistent approach to the measurement of resistant starch. Specifically, US 5,714,600 (July 31, 1992 priority) discloses the use of the McCleary method at col. 8 lines 25-27; and US 6,060,050 (September 16, 1994 priority) corresponding to the Brown WO 96/08261 reference applied by the Examiner also relies upon the use of the McCleary method at col. 6, table 3 to measure resistant starch levels.

B. The Rejection Under 35 U.S.C. §102(b) over Brown et al. WO 96/08261 Should be Withdrawn.

The rejection of claims 13, 14, 16-19, 21-23, 36 and 37 under 35 U.S.C. § 102(b), over Brown WO 96/08261 should be withdrawn as Brown does not disclose or suggest a method for regulating carbohydrate and fat metabolism comprising replacing at least 15% of the individual's daily carbohydrate intake with resistant starch and the substitution of unsaturated fat for saturated fat in the amounts and proportions recited.

While Table 9 of Brown discloses that the total amount of amylase resistant starch in the composition is about 90 grams (i.e., about 9% of the whole experimental diet, or about 11% of the total carbohydrate) applicants have now amended independent claim 13 to recite a minimum resistant starch proportion of 20% of starch thus avoiding anticipation by the disclosure of Brown. Further, claim 14 depending from claim 13 recites that the resistant starch comprises 15% of total carbohydrate. Accordingly, the anticipation rejection over Brown should be withdrawn.

C. The Rejection Under 35 U.S.C. §103(a) over Brown et al. WO 96/08261 Should be Withdrawn.

The rejection of claims 13, 14, 16-19, 21-23, 36 and 37 under 35 U.S.C. §103 over Brown should be withdrawn because it fails to render the subject matter of the amended claims obvious. While Brown Table 9 discloses the use of unsaturated safflower oil the reference also discloses the use of saturated fats including hydrogenated vegetable oils and mixtures of hydrogenated and non-hydrogenated vegetable oils, such as palm oil, for a method of extrusion to produce a granular product. As such there is no instruction to select unsaturated fats instead of saturated fats of use in the manner of the invention and the extrusion process teaches away from the present invention.

Specifically, Brown teaches only that a combination of resistant starch and probiotic microorganisms can promote the growth of microorganisms in the large bowel (i.e. resistant starch functions only as a carrier and a growth medium for the microorganisms). Thus, Brown does not disclose or teach that a combination of resistant starch and unsaturated fats when used as a replacement for a percentage of a daily intake of carbohydrates can result in the regulation of carbohydrate and fat metabolism resulting in a reduction in fat accumulation, lower plasma leptin concentration and reduced glucose and/or insulin levels.

Moreover, there is no suggestion that the invention described in Brown can promote a reduction in obesity and lead to enhanced sports performance. While applicants do not dispute that a pig would be expected to eat at least 113g of the composition as described in Table 9 of Brown, that disclosure does not teach that the feeding of the composition to pigs would lead to the regulation of fat metabolism and reduction in fat accumulation. Moreover, the person skilled-in-the art would not associate the feeding of the composition in Table 9 to pigs with any form of fat reduction. Instead, a person skilled-in-the-art it would assume that such feeding would promote an increase in body weight.

For these reasons the anticipation rejection under 35 U.S.C. §103 over Brown should be withdrawn and no new obviousness rejection under 35 U.S.C. §103 over Brown should be entered against claims 13, 14, 16-19, 21-23, 36 and 37.

D. The Rejection Under 35 U.S.C. §103(a) over Green et al., U.S. Patent 5,792,754 Should be Withdrawn.

The rejection of claims 13, 16-24, 36 and 37 under 35 U.S.C. §103(a) as being obvious over the disclosure of Green et al., U.S. Patent 5,792,754 should be withdrawn because Green fails to disclose or teach the composition of the claims as amended. Specifically, claim 13 has been amended to recite that the resistant starch content comprises at least 15% of the total carbohydrate content of the composition. As such, the proportion of resistant starch present in the Novelose high amylose starch of Green Example 4 fails to exceed this threshold.

Thus, Green is not cited as anticipating the claims because it does not actually disclose a composition which reads upon the claims. Instead Green suggests that a variety of starch types (including but not limited to resistant starch) can be combined with other components such as fat in various manners. As such it does not teach the selection and amounts of resistant starch and unsaturated fat of the claims. In the absence of such a teaching and in light of the unexpected results obtained by use of the compositions of the invention the rejection over Green is improper and should be withdrawn.

CONCLUSION

For all of the foregoing reasons, the rejection should now be withdrawn and a notice of allowance of all pending claims is respectfully solicited. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, she is invited to contact the undersigned attorney at the number indicated below.

Respectfully submitted,

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